

Applicants maintain that the policy behind the judicially-created doctrine of obviousness-type double patenting is the unjustified time-wise extension of a patent right to a common owner. When patent rights are vested in an owner, for example, by way of Assignment from inventors to an Assignee, the policy is applied so that a common owner of plural patent applications which allegedly claim embodiments which are no more than obvious variants of one another should not be allowed to obtain patent rights beyond the expiration date of the first-allowed application.

However, the doctrine cannot apply if plural applications claiming what are allegedly to be embodiments which are obvious variants of each other are not commonly owned because the rights belong to different owners. Therefore, the right to exclude for the different patents will be vested in different owners and thus, the patent rights would be in competition rather than held by a single entity.

In principle, if in fact the subject matter of the plural applications is no more than obvious variants of the same invention and neither application can serve as art to the other, it would appear that an inquiry under 35 U.S.C. §102(g) would appear to apply to the applications.

Moreover, because the instant application has an earlier effective filing date than U.S. Patent No. 5,356,810, on allowance, the patent which matures from the instant application would be an effective 35 U.S.C. §102(e) reference against U.S. Patent No. 5,356,810. Therefore, the validity of U.S. Patent No. 5,356,810 will be called into question and the mandate of the Patent Office of not allowing more than one patent on an invention ultimately will be addressed and resolved.

In any event, as stated throughout the record and repeated herein by reference in entirety, it is believed the obviousness-type double patenting rejection is improper and must be removed.

In item 20 bridging pages 4 through 6 of the Office Action, the claims remain rejected under 35 U.S.C. §112, first paragraph.

The rejection is traversed for the following reasons.

The Examiner maintained that deposits are required.

However, Applicants have refuted that position to the extent that all of the starting materials for practicing the instant invention are readily available to the artisan. For example, numerous strains of *Phaffia*, both wild-type and astaxanthin-overproducing strains, are available from depositories without restriction. All of the reagents for growing and treating the yeast are commercially available. Moreover, a method for obtaining a mutant *Phaffia* expressing high levels of astaxanthin is provided in the instant specification. In fact, a method which can be used to obtain a mutant *Phaffia* as claimed in the instant application is patented, see U.S. Patent No. 5,182,208.

The law is clear that a deposit is not required if the specification teaches a reproducible method for practicing a claimed invention and if the starting materials are readily available. That situation clearly applies to the instant specification.

To make the point ever so clear, a Rule 132 Declaration is of record, see, for example, the Declaration filed 1 April 1988 and executed 4 November 1997. That Declaration demonstrates that practicing the methods set forth in the instant specification, over 100 examples of mutant *Phaffia* containing high levels of astaxanthin were obtained.

Clearly the evidence is highly probative on the reproducibility of the teachings of the instant specification and demonstrate that an artisan on practicing, for example, the patented

method of obtaining mutant *Phaffia* with enhanced astaxanthin content as set forth in the instant specification and using available starting materials, will without undue experimentation obtain *Phaffia* within the scope of the claimed invention.

Accordingly, deposits are not required, the instant specification is enabling, the claims are enabled and the rejection should be removed.

In item 21 on page 6 of the Office Action, claims 25-34 were rejected under 35 U.S.C. §112, first paragraph for an alleged want of enablement.

The rejection is traversed for the following reasons.

The instant invention can be practiced by use of, for example, a patented method for obtaining *Phaffia* with enhanced astaxanthin content. Therefore, the instant specification teaches a reproducible method for obtaining *Phaffia* within the scope of the claimed invention. There can be no doubt that the instant specification is enabled by clearly teaching how to make a *Phaffia* of interest using materials available to the artisan.

The instant specification provides numerous actual examples of *Phaffia* which fall within the scope of the instant claims. Thus, the application as filed clearly demonstrates that *Phaffia* with graded levels of astaxanthin above that found in wild-type *Phaffia* can be obtained by the practice of the instant invention. It is not seen how the instant specification which has resulted in two patents can be said to be non-enabling.

Moreover, as referred to hereinabove, a Declaration is of record demonstrating that by practicing the methods set forth in the instant specification, over 100 other examples of *Phaffia* with enhanced astaxanthin content which fall within in the scope of the instant claims were

made. Clearly the method of the instant specification is reproducible and evidence of over 100 different examples of *Phaffia* which fall within the scope of the instant claims has been provided to the Examiner.

It is unclear how such persuasive evidence cannot be considered to show that the instant specification teaches how to make a claimed *Phaffia*.

The Examiner also relied on the Fisher case. However, an examination of the facts revealed that the Appellant in the Fisher case disclosed only one species of a claimed genus and therefore support for a genus claim was found to be lacking.

On the other hand, the instant application and the Declaration evidence of record demonstrate numerous examples of *Phaffia* which fall within the scope of the instant claims. Therefore, the instant application, unlike the facts of the Fisher case, provides numerous examples which fall within the scope of the claimed invention. The instant invention is fully supported.

The Examiner relied on the Fiers case. However, that case is not all together applicable as the subject matter of Fiers was a DNA, an informational biomolecule wherein the actual nucleic acid base sequence is of import if the DNA is claimed.

On the other hand, the instant application relates to a specific type of yeast, *Phaffia*, and a specific recognizable mutant of that *Phaffia*. By definition, a taxonomic name provides clear and distinctive identification of the yeast of interest. Moreover, Applicants are claiming only one specific characteristic arising from mutation and selection of such *Phaffia* and that is those *Phaffia* which have an enhanced content of astaxanthin. Therefore, the *Phaffia* of interest are

clearly identified by the taxonomic description of, and inherently all of the characteristics which exist in, a Phaffia.

Moreover, the sentence recited by the Examiner was extracted from a discussion on written description and not enablement. That is particularly relevant as the party to which that statement related to (Revel) was claiming a DNA but the specification did not teach a DNA, instead teaching only an mRNA. The Revel application then went on to state that a corresponding cDNA can be obtained.

Clearly Revel did not comply with the written description requirement as to the DNA of the count because by the very words of the Revel application, a DNA was not made at the time the application was filed.

In any event, the rejection relates to enablement not to written description.

The Examiner also equated a Phaffia with a DNA and believed that because description of a DNA requires knowledge of the base sequence, a Phaffia requires a precise definition such as by structure, formula, chemical name or other physical properties.

Again, the Examiner relied on language of the Fiers case relating to written description and not to enablement.

The Phaffia of interest is identified by a unique taxonomic descriptor and is readily identifiable as such. All that is needed to identify a microorganism is a name. Moreover, the claimed Phaffia have a readily definable characteristic, namely enhanced astaxanthin content, which can be assessed visually. Thus, the Examiner is reminded that the subject matter of

interest is a *Phaffia* with enhanced astaxanthin content, not just a mutant yeast strain which produces pigment.

Applicants are not obligated to provide evidence of all possible embodiments within a genus, that is not the standard to prove enablement, see, The Training Materials for Examining Patents, section relating to enablement, page 28.

The Examiner has not provided any explanation as to why the representations of enablement in the instant specification and in the record are unbelievable. Moreover, the Examiner has not provided any evidence in support of his position. Applicants believe there is no basis, on considering the record as a whole, to conclude there is a lack of enablement. MPEP 2164.04 and MPEP 2164.05.

The Examiner also relied on the *Wands* case with respect to enablement.

However, the *Wands* case is clearly in support of the enablement of the instant application. For example, *Wands* is related to the making of monoclonal antibodies which requires a fusion of two cell types, a culturing and growth of the hybrids of that fusion process and then a very detailed screening of the surviving hybrids to determine which produce monoclonal antibody and to determine which of those cells which produce monoclonal antibody, produce a monoclonal antibody of interest. The Federal Circuit found that while the process for making a monoclonal antibody can be long and tedious, it is a routine method and does not entail undue experimentation.

One of the methods for making mutant *Phaffia* of interest is to expose *Phaffia* to a mutagen and a selection agent and then to select those *Phaffia* which have enhanced astaxanthin content. That screening process can be mere visualization of cultures.

The mere visualization of cultures is much simpler than the screening process involved in the making of hybridomas which requires generally an RIA or ELISA for determining which cells secrete monoclonal antibody and then a similar if not same type of test to determine the specificity of those monoclonal antibodies. The method is clearly taught in the instant specification and no undue experimentation is required to practice the instant invention.

The actual experimentation required to obtain a Phaffia of interest is less involved than that set forth in Wands. Therefore, if Wands was found enabling for making hybridomas then clearly the instant method which technically is simpler than that of making monoclonal antibodies must be considered enabling as well.

Clearly, no undue experimentation is required to practice the instant invention. That is demonstrated by the actual examples of Phaffia falling within the scope of the instant claims provided in the specification as filed, as well as the numerous other examples of Phaffia which fall within the scope of the instant claims which were made practicing the instant specification as provided in the Declaration of record. Moreover, an artisan on reading that instant specification would know how to make and how to use the claimed invention.

If the Examiner considers all of the evidence relating to the issue of enablement and undue experimentation which is of record, the Examiner will find that on consideration of the evidence as a whole, which is the standard by which the Examiner must assess enablement, that clearly a prima facie case of non-enablement has not been made and the instantly claimed invention is enabled.

Accordingly, to then, the instant specification is enabling, the claims are enabled and the rejection must be removed.

Then on page 9 of the Office Action, the Examiner raised a new rejection under 35 U.S.C. §112, first paragraph alleging that the instant invention was not described in the specification to demonstrate that the inventors were in possession of the claimed invention at the time the application was filed.

Essentially, the Examiner questioned whether the inventors were in possession of the total invention as claimed. The Examiner indicated that there must be evidence that the specific mutant microorganisms were in fact available and described adequately in the specification at the time the application was filed.

The rejection alleging want of written description is traversed for the following reasons.

Applicants fully believe that the instant specification clearly allows persons of ordinary skill in the art to recognize that the named inventors were in possession of the claimed invention at the time the first filed parental application, U.S. Serial No. 229,536 (hereinafter, "the '536 application"), was filed. The instant specification clearly conveys with reasonable clarity to those skilled in the art that the invention as claimed, namely, *Phaffia* with enhanced astaxanthin content, was in fact described in the instant specification in compliance with the statute.

The instant specification provides a clear and reproducible teaching of how to make a claimed *Phaffia* with enhanced astaxanthin content and provides numerous actual examples of such *Phaffia* which fall within the scope of the claimed invention.

Moreover, as provided in the attached second Declaration of Stephen Hiu (the curriculum vitae of Dr. Hiu will be filed shortly), the over 100 examples of *Phaffia* falling within the scope of the instant claims which were discussed in the first Declaration of Hiu, were made as provided

REQUEST FOR RECONSIDERATION

U.S. Appln. No.: 08/458,019

by a method set forth in the instant specification and were obtained prior to the filing of the '536 application on 8 August 1988.

Thus, the instant specification provides sufficient written description that the claimed invention was in the possession of the inventors at the time the '536 application was filed and moreover, on reading the record of the instant application, by way of the Rule 132 Declarations of record, clearly an artisan would well recognize that the claimed invention was in the possession of the named inventors at the time the '536 application was filed.

Once again, the Examiner referred to the Fiers case which relates to chemical compounds and not to microorganisms, such as *Phaffia*.

Nevertheless, the instant application provides a taxonomic definition of *Phaffia* of interest and that definition provides a clear definition explicitly and inherently, based on all of the inherent characteristics of a strain which comport with that taxonomic description, of the subject matter of interest.

Moreover, the instant specification provides a plurality of examples of a *Phaffia* which have enhanced astaxanthin content. That clearly defines the subject matter of interest and an artisan would be able to see, knowing that the starting material are available in the art, that the invention was practiced to a full extent. Numerous examples of *Phaffia* which fall within the scope of the claims are provided in the instant specification and thus clearly the inventors were in full possession of the claimed invention at the time the '536 application was filed.

The Examiner relied on the Lockwood case on the issue of written description. Lockwood relates to a computer reservation system which likely could be described by means of a diagram, structure, formula and so on.

The instant invention relates to a particular kind of yeast which is identified by the scientifically accepted method of nomenclature. The unique name, Phaffia, is fully descriptive and identifying of a yeast of interest. Therefore, the scientific name describes a yeast of interest.

The instant invention relates to specific mutants of Phaffia which overproduce a pigment, astaxanthin, as claimed. The instant specification is replete with teachings relating to Phaffia which overproduce astaxanthin. Therefore, the specification adequately describes the claimed invention.

The Smythe case relied on by the Examiner demonstrates that not all embodiments need be described or enabled to satisfy either the enablement or written description requirement.

Smythe claimed "inert fluid" but disclosed only gases. Nevertheless the CCPA held that one of skill would have interpreted the generic term to include liquids as well. Therefore, despite the lack of explicitly teaching a liquid in the specification, the term "inert fluid", was found to describe and to enable a liquid as well as a gas.

Finally, the Examiner relied on the Wilder case for the proposition that the application must provide a description of the invention not an indication of a result that one might achieve if one made that invention.

Indeed, the instant invention relates to Phaffia which overproduces astaxanthin. The instant specification teaches that such yeast were in fact made prior to the filing of the '536 application in 8 August 1988.

It is believed the Examiner has not provided any evidence why an artisan would not recognize the instant specification describes the invention as claimed, namely, Phaffia overproducing astaxanthin. MPEP 2163.04. All of the claim limitations are described.

Therefore, clearly a lagally sufficient written description is provided in the instant specification, the requirements of the Patent Statue have been complied with and the rejection can be removed.

CONCLUSION

Applicants have endured extended prosecution in the instant application and firmly believe on the basis of having patents issue in previous filed applications in the patent family that the claimed invention is in full compliance with the Patent Statue and clearly is patentable.


Therefore, reexamination, reconsideration in view of the arguments herein and the record as a whole, withdrawal of the rejections and early indication of allowance are solicited earnestly.

If any issues remain outstanding, the Examiner is urged to contact the undersigned at the local exchange indicated hereinbelow so that a hasty resolution and allowance can be obtained without further delay.

REQUEST FOR RECONSIDERATION
U.S. Appl. No.: 08/458,019

Applicants hereby petition for any extension of time which may be required to maintain the pendency of the instant application and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,


Dean H. Nakamura
Registration No. 33,981

SUGHRUE, MION, ZINN,
MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, N.W.
Washington, D.C. 20037-3213
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

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